A quick, sensitive, in-situ test to detect residual proteins using fluorescence
Making it easy to check the cleanliness of reprocessed surgical instruments
The ProReveal Fluorescence Protein Detection Test has been developed in response to the need to find a more sensitive and accurate method of checking for residual proteins that can remain on surgical instruments after the washer disinfection process.

The ideal solution for an SSD

Recent research into possible methods for checking of surgical instruments has shown that in-situ fluorescent testing methods can produce a very high level of confidence into the effectiveness of the washer disinfecter process. The ProReveal Protein Detection Test is a highly sensitive fluorescence-based patented test for checking the presence of residual protein on surgical instruments after going through any washer disinfecter process.

The test is cost-effective and delivers objective, visual and quantifiable results and removes any doubt as to whether the washing decontamination process has left instruments clean enough to meet residual protein level standards. The frequency of checking instruments is typically determined by either local or national guidelines.

And this is important because

The quality of any washer disinfection process is dependent on a number of variables: type of washer disinfecter, the process, instrument position in the washing tray, water quality, detergent, to name just a few. Hence, an effective check process is required to ensure that surgical instruments have been cleaned to the required standard during the washing process.

Commonly used tests include on-instrument swab tests or visual inspection. It has been found that neither of these can detect the lower levels of protein that can remain on an instrument after washing and which can be a major source of cross infection particularly with prions such as vCJD. The added problem with any swab test is that only part of an instrument can be tested and the results remain very subjective as to whether the operator has performed the test correctly and interpreted the results accurately. Instruments that remain 'dirty' after washing can be a prime source of infection and can result in cancelled operations, closed theatres and of course worse still have a catastrophic effect on patient safety.
A common perception is that the sterilisation process makes an instrument safe to re-use. However, this has been shown to not be the case. The main reasons why sterilisation may not be effective are described below in more detail.

**Prions**
Variant Creutzfeld-Jacob Disease (vCJD) is transmitted by ‘prions’ (infectious proteins) which are resilient to current instrument washing processes and steam sterilisation and also have a high affinity to steel surfaces making it difficult to remove ‘prions’ from surgical instruments.

**Endotoxins**
Gram negative bacteria release endotoxins when they denature and can be dangerous due to their association with systemic inflammatory infections such as sepsis. Endotoxins are extremely heat stable and they often stay viable even after conventional autoclaving.

**Bioburden**
It is recommended that the monitoring of bioburden (the amount of contaminant present on any item) present on a surgical instrument prior to sterilisation is critical in maintaining the effectiveness of the sterilisation process.
The ProReveal Process

How it works

The ProReveal test is simple to perform, requires little training and can be completed in under 4 minutes.

Results

The ProReveal offers two modes to the user ‘inspection’ and ‘control’.

The ‘inspection’ mode simply displays the total amount of protein present on the whole instrument.

The ‘control’ mode displays a pass or fail result or you can select to show a traffic light warning.

In this test 11.6 µg of residual protein has been found remaining on the instrument after washing.

In this test upper and lower limits of protein are set and the result shows a warning that the level of protein found falls between the limits. In this case the washer disinfector process probably needs to be further optimised.
Reports

The ProReveal has a 3D viewing option which allows the user to clearly see the amount and position of any residual protein left on the instrument after washing.

Data from every test can be stored within the hard disk of the ProReveal or it can be printed out as a pdf report.

Any data saved to the hard disk of the ProReveal can be exported as a .csv, .txt or Excel file for archiving or for further analysis.

Using ProReveal in ‘diagnostics’ mode

Using an optional barcode reader, a range of different fields can be linked to the test data.

For example:
- Detergent type
- Tray and tray position
- User
- Washer disinfector
- Washing process

The data will, over time, allow for a ‘picture’ of how the washer disinfector process is performing and help to highlight if the need for any optimisation is required. The data will also help to pin-point where any changes to the process might have been made which could have affected the quality of the washer process.

The data will allow SSD managers to continuously monitor the washer disinfector process and identify any areas for optimisation if required.

This diagnostic tool offers quantitative data to help determine the optimum conditions for the SSD washing process.
**ProReveal Tags**

*ProReveal* Tags are used in conjunction with *ProReveal*. Each tag has a known amount of protein on them. Tags are placed in the washing machine in the trays alongside the instruments and washed using standard washing protocols. After the washing process the tags are tested to determine the level of residual protein remaining. The level of any residual protein left on the tag is a good indication as to whether the washer disinfection process needs to be optimised.

**Other Applications for ProReveal**

- Washing machine manufacturers to help them design and optimise their machines and processes
- Surgical instrument manufacturers for checking to see if the design of their instruments could lead to easier washing
- Detergent manufacturers who wish to improve their chemistries
- Ultrasonic machine manufacturers who wish to check the effectiveness of their products
- Single use surgical instrument importers who want to check the cleanliness of imported instruments
### Key Features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Benefit</th>
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<tbody>
<tr>
<td>Whole instrument can be measured</td>
<td>Assurance that the whole instrument has been tested</td>
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<td>Quantitative result</td>
<td>Peace of mind - no need to worry about interpretation of results</td>
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<tr>
<td>Instant result</td>
<td>Test performed in less than 4 minutes</td>
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<td>Easy to use</td>
<td>No additional training required</td>
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<td>Report generation</td>
<td>Full traceability for quality control - reports can be generated for all images saved and are downloadable to a USB stick</td>
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<td>3D visual display as to the location of the proteins and how much is present</td>
<td>Pin points difficult areas to clean</td>
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<td>Highly sensitive test</td>
<td>Detects less than 50ng of residual protein</td>
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<td>Programmable</td>
<td>ProReveal can be set for user defined levels to meet any local or national guidelines</td>
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<tr>
<td>Network port</td>
<td>Suitable for connection to internal hospital network facilities</td>
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